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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/236,402 05/02/94 DEAN

R 91875B

EXAMINER

DAVENPORT, A

18M2/0222

ART UNIT

PAPER NUMBER

ALLEGRETTI AND WITCOFF LTD
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1811

DATE MAILED:

02/22/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 23 are pending in the application.
Of the above, claims 7, 8, 11-18, and 22-23 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-6, 9, 10 and 19-21 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Claims 1-23 are pending in the instant application. Claims 1-6,9,10 and 19-21 are under consideration. Claims 7,8,11-18,22 and 23 have been withdrawn from further consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-6,9,10 and 19-21 under 35 USC §112, first paragraph is maintained. The rejection is maintained for essentially the same reasons as the rejection under this statute and subsection as set forth in the previous office action. Applicant's arguments have been fully considered but were not deemed persuasive for the following reasons. Applicants argue the *Fisher* case. For example, "Applicant respectfully contends that the teachings of the *Fisher* case are inapposite to his invention, in general because of the admitted advances in the small molecule pharmaceutical arts over the past twenty-five years, and specifically, because he has crafted his claim language to exactly inform the future on the structural and functional characteristics of the reagents that fall within the scope of his claims." Applicants go on to say that the *Fisher* case does not stand for the proposition that the instant case is in any way analogous to the *Fisher* teachings. The *Fisher* case, although 25 years old, was cited for the general teaching that peptides are unpredictable, unless the proper and sufficient guidance is set forth. This is also true today even though there are better techniques for testing and analysis of peptides. In the instant case applicants have not set forth the proper and sufficient guidance such as representative examples, etc., that would assure one of skill in the art that the peptides or

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reagents as set forth, in view of the language crafted to claim said peptides or reagents, would fall within the scope of the claims.

- Applicant has stated that he believes the term “specific binding peptide” would be understood by one of ordinary skill in the art and has provided references with said terminology. The examiner agrees that the terminology is understood by those of skill in the art. The instant rejection of said terminology under 35 USC §112, first paragraph is not related to the clarity of the terminology, it is related to the scope of said terminology in view of the instantly enabling disclosure. In claim 1, applicant claims a “specific binding compound” that is less than 10,000 daltons which is even broader than the term “specific binding peptide”. In claim 5, applicants claim a “specific binding peptide” comprised of 4 to 100 amino acids with no further guidance as to the structure. The scope of said “specific binding peptide or compound” is broader than the enabling disclosure and therefore lacks enablement. It would require an undue amount of experimentation to determine the peptides which can recognize a component, any unrestricted component, at any unrestricted target site and bind specifically thereto without the proper and sufficient guidance in the instant specification to identify and utilize the structure of said peptides or compounds. Applicants discuss the thiol-containing moieties that have been exemplified. The examiner agrees with the applicants assertions concerning the thiol-containing components of the radiolabel complexing moieties as set forth. The rejection concerning the thiol-containing moiety is withdrawn in view of exhibits B-M as set forth in the instant

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response. Applicants have not set forth either the proper and sufficient teachings or guidance and/or representative examples to enable the instant claims. There is no showing that the instant radionuclides or radiolabeled complexing moieties would deliver said radionuclides or radiolabeled complexing moieties to the site of the target cells. This is a lack of enablement. The instant invention reagents and/or radiolabeling moieties are broader than the enabling disclosure. The rejection is maintained.

Claims 1-6, 9, 10, and 19-21 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis Davenport whose telephone number is (703) 308-4002. The examiner can normally be reached on Tuesday -Friday from 6:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecelia Tsang, can be reached on (703) 308-0254. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Davenport/sg

October 27, 1997


AVIS M. DAVENPORT
PRIMARY EXAMINER
GROUP 1800